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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,499	09/23/1999	MICHAEL S. O'REILLY	05213-0640	9544

23594 7590 10/11/2002

JOHN S. PRATT  
KILPATRICK STOCKTON LLP  
1100 PEACHTREE  
SUITE 2800  
ATLANTA, GA 30309

EXAMINER
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HUFF, SHEELA JITENDRA

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/11/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/405,499

Applicant(s)

O'REILLY ET AL.

Examiner

Sheela J Huff

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 52-55,57-66 and 68-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 52-55,57-66 and 68-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/8/02 has been entered.

### ***Response to Arguments***

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

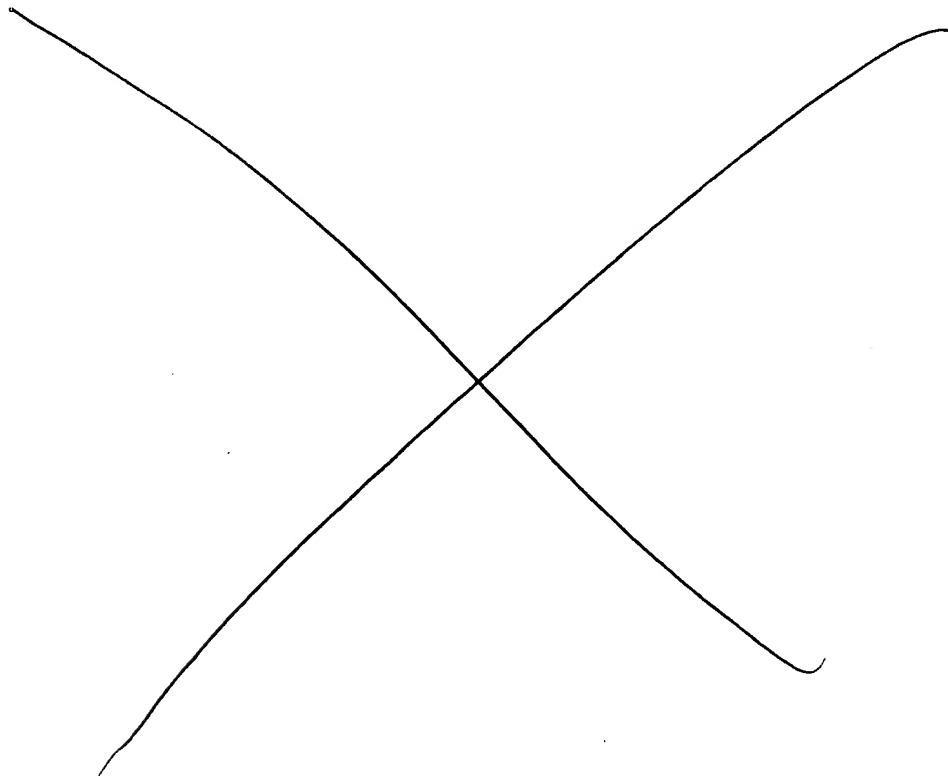
Claims 52-55, 57-66 and 68-73 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7

and 17-23 of U.S. Patent No. 5854205. The reasons for this rejection are of record in paper no. 5, mailed 12/19/00.

Applicant indicates that they will file a terminal disclaimer, when appropriate.

Claims 52-55, 57-66 and 68-73 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of US. Patent No. 6346510. The reasons for this rejection are of record in paper no. 5, mailed 12/19/00.

Applicant indicates that they will file a terminal disclaimer, when appropriate.



***Claim Rejections - 35 USC § 112***

Claims 52-55, 57-62 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION. The reasons for this rejection are of record in paper no. 9, mailed 7/19/01.

Applicant argues that the claims are directed to an antiangiogenic fragment of an NC1 region of a collagen protein. The claims are directed to a protein comprising an antiangiogenic fragment and are not solely directed to the fragment.

Claims 52-55, 57-66 and 68-73 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for endostatin ( as defined by its molecular weight, N-terminal sequence and ability to inhibit endothelial cell proliferation in vitro), does not reasonably provide enablement for a protein comprising or consisting of any fragment of NC1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The reasons for this rejection are of record in paper no. 9, mailed 7/19/01.

Applicant argues that they provide a roadmap for discovering additional anti-angiogenic fragments of a NC1 region of collagen and refer to Examples 1-3 and the CAM assay and a declaration from Dr. Olsen. Applicant's position is that in view of the fact that the instant specification showed that the NC region of collagen XVIII had anti-angiogenic activity, one of skill in the art would immediately recognize that the other collagens would also have anti-angiogenic activity. While it is true that each collagen does have a NC domain, the specification only shows that NC domains containing SEQ ID No. 1 or 2 have anti-angiogenic activity. These sequences are found in collagen XVIII, however it is clear that collagen XV has very little homology to SEQ ID No 1 or 2. A sequence search of SEQ. ID No 1 against the database provided no hits. A sequence search of SEQ ID No. 2 against the database showed that collagen XV 42.6% homology. Thus, one of skill in the art, after looking at applicant's specification and the sequence homology between collagen XV and collagen XVIII ( which has SEQ. ID No. 1 or 2) would not readily envision that collagen XV would possess anti-angiogenic activity. In fact, a fair and reasonable reading of the sequence searches only shows that collagen I has homology to SEQ ID No. 1 and/or 2. Therefore, in view of structural characteristics, it is clear that a close look at the sequences of the different collagens and at collagen XVIII (which is where SEQ ID No. 1 and 2 were derived), it is clear that the different collagens do not all possess a sequence similar to these. Thus, while each collagen does possess an NC domain, it is clear that not all of them have SEQ ID No. 1 or 2. Thus, there is no roadmap.

Furthermore, there is no guidance regarding what sequence of amino acids found within even a defined fragments would be predicted to inhibit endothelial cell proliferation.

There is no guidance regarding which fragments, of what size, from what region, within the C-terminus would be predicted to inhibit endothelial cell proliferation. There is no guidance regarding which collagens are predicted to possess such sequences. Further, there is no guidance regarding the content of the rest of the protein, in addition to the amino acid fragment. The specification discloses that not only is the sequence of the fragment vital to activity, but also that additional sequences added to the definitive fragment are vital.

Claims 52-55, 57-66 and 68-73 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The reasons for this rejection are of record in paper no. 9, mailed 7/19/01.

Applicant's arguments have been addressed above.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 52-54, 57-62 remain rejected under 35 U.S.C. 102(e) as being anticipated by Olsen et al US 5643783 (filed 12/1/93). The reasons for this rejection are of record in paper no. 9, mailed 7/19/01.

Applicant argues that the claims are directed to an antiangiogenic fragment of an NC1 region of a collagen protein. The claims are directed to a protein comprising an antiangiogenic fragment and are not solely directed to the fragment.

### ***Conclusion***

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is (703) 305-7866. The Examiner can normally be reached on Monday and Thursday from 5:30am to 2:00pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Tony Caputa, can be reached on (703)308-3995.

The FAX phone number for the group is (703)308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [anthony.caputa@uspto.gov].

All Internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Sheela J. Huff

October 10, 2002

  
Sheela J. Huff  
Primary Examiner